

REMARKS/ARGUMENTS

Initially, Applicant would like to express appreciation to the Examiner for the detailed Official Action provided.

Applicant submits that the instant amendment is proper for entry after final rejection. Applicant notes that no question of new matter or any new issues are raised in entering the instant amendment of the claims and that no new search would be required.

Moreover, Applicant submits that the instant amendment places the application in condition for allowance, or at least in better form for appeal.

Accordingly, Applicant requests that the Examiner enter the instant amendment, consider the merits of the same, and indicate the allowability of the present application and each of the pending claims.

Upon entry of the above amendments, claims 1, 3, 6-8, 10, 15 and 20 will have been amended. Claims 1-20 are currently pending. Applicant respectfully requests reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

In the Official Action, the Examiner has maintained the rejection of claims 1, 3, 8-13, as well as previously added claim 14, under 35 U.S.C. § 102(b) as being anticipated by HOFFMAN et al. (U.S. Patent No. 5,021,056); and

Claims 15 and 17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by newly-applied HUEBNER et al. (U.S. Pub. 2004/0102788).

Without acquiescing to the propriety of the Examiner's rejections, claims 1

and 15 have been amended solely in order to expedite prosecution of the present application.

In this regard, Applicants note that HOFFMAN and HUEBNER do not disclose each and every element as recited in amended claims 1 and 15, respectively. In particular, claims 1 and 15 both generally recite a device for ligament reconstruction including, inter alia, a connector which connects said rear-end and said tip...and said rear-end being configured to drive said tip and connector into a bone.

Applicant submits that neither HOFFMAN nor HUEBNER discloses the above-noted combination of elements.

In regard to the rejection which relies on HOFFMAN as a basis (i.e., which includes the rejection of claim 1), the Examiner asserts that HOFFMAN discloses the presently claimed device for ligament reconstruction. More particularly, in setting forth the rejection, the Examiner has indicated that HOFFMAN discloses a device having a tip, connector, and rear-end (*see* the included Figure, on page 4 of the Official Action). Additionally, the Examiner considers element 54 as providing the tip having a generally rectangular shape, and element 46 as providing the tip having a generally elliptical shape. Further, the Examiner takes the position that reference numeral 64 corresponds to a second generally parallel through-hole provided in the tip.

However, contrary to the Examiner's assertions, Applicant submits that the device of HOFFMAN is structurally very different from the present claimed

invention.

In particular, HOFFMAN discloses that the “transverse alignment or first guide assembly 10 is positioned mediolaterally on the upper tibia 138, as shown in FIG. 25, with the upper end of the assembly touching the tibial locating needles. The clamp arm 44 can be swung to a position almost normal to the clamp arm 42, by virtue of the slot 30 in order to facilitate this mounting of the assembly on the tibia. The two clamp plates 54, 56 are brought into engagement with opposite sides of the tibia by rotation of the knobs 34, 36 driving cylinders 50, 52 along the threaded shaft 32. They are tightened until the assembly is firmly positioned on the tibia with the protrusions 68 providing a biting grip. The assembly is stabilized by drills 19 inserted into the bone through holes 64. Next a transverse bore is drilled completely through the tibia using one of the guide holes 62” (see, Column 5, lines 3-19).

In other words, the device of HOFFMAN, which the Examiner considers to be a ligament reconstruction device, is only a guide system and does not penetrate the bone. Thus, HOFFMAN does not disclose at least the ear-end (of the device for ligament reconstruction) being configured to drive said tip and connector into a bone which receives ligament reconstruction, as recited in amended claim 1.

Further, Applicant submits that the Examiner continues to be inconsistent in his interpretation of the “tip” of the device for ligament reconstruction. In this regard, in setting forth the rejection, the Examiner continues to interpret the “tip” as comprising reference numerals 32, 46, and 54, for the purpose of asserting that

the tip includes first and second parallel through-holes (i.e., 32 and 64). However, for the purpose of asserting that the “tip” has a general elliptical cross-section, the Examiner interprets the cross-section as only being a cross-sectional end of the device 32. Therefore, the Examiner’s interpretation of HOFFMAN is inconsistent.

That is, since the Examiner considers the tip to be the entire end of the device (as characterized by the Examiner on page 4 of the Official Action); the cross-section, as purportedly disclosed in HOFFMAN, would be comprised of several geometrical cross-sections having different dimensions. Thus, HOFFMAN does not disclose “a tip which has a generally elliptical or rectangular cross-section,” as recited in claim 1.

In regard to the rejection which relies on HUEBNER as a basis (i.e., which includes the rejection of claim 15), in setting forth the rejection, the Examiner takes the position that HUEBNER discloses the presently claimed tip (which the Examiner considers to be the end of the device provided with holes 59), rear-end (indicated by the Examiner as being 76), and connector (indicated by the Examiner as being 62).

However, contrary to the Examiner’s assertions, Applicant submits that the device of HUEBNER is structurally very different from the present claimed invention.

In particular, HUEBNER discloses that the “[g]uide portion 76 may include among others any structure connected to coupling portion 74 and configured to define guide axis 62. The guide axis may be any path along which a tool or

fastener may be guided physically by the guide portion. Accordingly, the guide axis may be defined by a guide element 60 having a passage, such as a channel, through which a tool or fastener may be advanced axially. The passage may restrict substantial lateral movement of the tool or fastener by having a diameter slightly larger than a tool and/or fastener for which the passage is configured. The guide element may be an integral component of the guide portion, such as an aperture or opening formed in the guide portion, or may be formed by a separate component, such as a tube (or cannula) of any suitable shape and size disposed in a frame 79 of the guide portion. The tube may direct a drill bit, a fastener (such as a bone screw), and/or a driver (such as screwdriver), among others, through the guide element and along guide axis 62 through intervening bone and then to an oppositely situated bone-repair device” (see, paragraph [0033]).

In other words, similar to the device of HOFFMAN, HUEBNER also discloses a guide system which does not penetrate the bone. Thus, HUEBNER does not disclose at least the ear-end (of the device for ligament reconstruction) being configured to drive said tip and connector into a bone which receives ligament reconstruction, as recited in amended claim 15.

Further, Applicant notes that “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is

served by the recited element, ingredient or step.” See, In Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc., 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004).

Additionally, in regard to the Examiner’s rejection of method claims 10-13, as discussed supra, HOFFMAN and HUEBNER do not disclose at least at least the rear-end (of the device for ligament reconstruction) being configured to drive said tip and connector into a bone which receives ligament reconstruction, and is therefore, incapable of performing the method recited in claims 10-13.

Further, Applicant notes that “[a]bsent a disclosure in a single reference of each and every element recited in a claim, a *prima facie* case of anticipation cannot be made under 35 U.S.C. § 102. Since the applied reference fails to disclose each and every element recited in independent claims 1 and 15, and method claim 10, as well as claims 2-9, 11-14 and 16-20 respectively depending therefrom, these claims are not anticipated thereby. Further, all pending dependent claims recite additional features that further define the present invention over the prior art. Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102 and allow all pending claims in the present application.

In the Official Action, the Examiner has rejected claims 2 and 4-7 under 35 U.S.C. § 103(a) as being unpatentable over HOFFMAN; and

Claims 16 and 18-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over HUEBNER.

Firstly, Applicant submits that the aforementioned claims are at least patentable due to their respective dependences from claims 1 and 15, and method claim 10, for the reasons noted above. In this regard, Applicant notes that the Examiner has provided no proper reasoning for correcting the above-noted deficiencies in the teachings of HUEBNER. Applicant further submits that the Examiner's assertion that the combination of elements recited in claims 2, 4-7, 16 and 18-20, only involve discovering obvious optimum or workable ranges, does not provide any teachings which could reasonably be characterized as curing the above-noted deficiencies in the teachings of HUEBNER. In this regard, Applicant submits that HUEBNER, alone or in any proper combination, does not disclose, inter alia, the tip having a generally elliptical or rectangular cross section elongated in a direction in which the through-holes thereof are juxtaposed, as recited in claim 1

In particular, Applicants note that "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Further, although the Examiner continues to reject the aforementioned claims as being merely a matter of obvious optimization, Applicant submits that the Examiner still has not made such showing, but has relied on a conclusion of obviousness that is not supported by any evidence or reasoning. Further, the

Examiner assertion that the use of the term “preferable” in the written description somehow indicates that the features recited in claims 2, 4-7, 16 and 18-20 are not critical is unsupported by any factual evidence.

In this regard, the written description clearly discusses the advantages of the present claimed device for ligament reconstruction.

More particularly, at least one advantage of the presently claimed invention is that the tip and body portion have a generally elliptical or rectangular cross section rather than a simple round cross section. Therefore, the bone cavity to be formed in the bone has a cross section close to the cross section of an ordinary ligament, so that the outer peripheral surface of the ligament is entirely brought into proximity to the interior surface of the bone cavity. Hence, the ligament can be bonded to the bone with a greater bonding force in a shorter period of time (see, Page 3, lines 1-6).

Thus, it is apparent from the present Specification that the particular geometries of the device for ligament reconstruction, as recited in claims 2, 4-7, 16 and 18-20, will at least have an advantageous effect on ligament bonding, in addition to the advantages of the invention defined in independent

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 103 and allow all pending claims in the present application. Further, if the Examiner decides to maintain the aforementioned rejection of claims 2, 4-7, 16 and 18-20, Applicant respectfully requests that the Examiner provide an appropriate teaching reference disclosing the recited features.

In view of the arguments herein, Applicant submits that independent claims 1 and 15, and method claim 10, are in condition for allowance. With regard to dependent claims 2-9, 11-14 and 16-20, Applicant asserts that they are allowable on their own merit, as well as because of their respective dependencies from independent claims 1 and 15, and method claim 10, which Applicant has shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.

SUMMARY

Applicant submits that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicant has argued the allowability of the claims and pointed out deficiencies of the applied reference. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicant notes the status of the present application as being an after final rejection and with respect to such status believes that there is a clear basis for the entry of the present amendment consistent with 37 C.F.R. § 1.116. Applicant notes amendments after final are not entered as a matter of right; however, Applicant submits that the present amendment does not raise the question of new matter. Moreover, the present amendment clearly places the present application in condition for allowance.

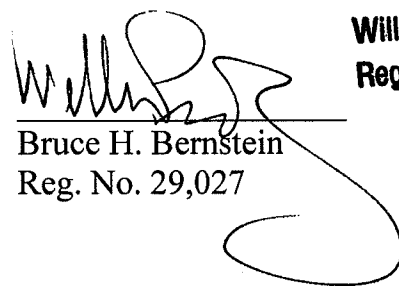
Applicant notes that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be

considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

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